

04-23-04

HDP/SB/21 based on PTO/SB/21 (08-00)

Please type a plus sign (+) inside this box → ☐

## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

<b>TRANSMITTAL FORM</b> (to be used for all correspondence after initial filing)	<b>Application Number</b>	10/735,449	
	<b>Filing Date</b>	12-12-03	
	<b>First Named Inventor</b>	Shawn D. Roman et al.	
	<b>Group Art Unit</b>	3731	
	<b>Examiner Name</b>	Unknown	
<b>Total Number of Pages in This Submission</b>		<b>Attorney Docket Number</b>	5490-000259-COB

### ENCLOSURES (check all that apply)

<input type="checkbox"/> Fee Transmittal Form  <input type="checkbox"/> Fee Attached  <input type="checkbox"/> Amendment / Response  <input type="checkbox"/> After Final  <input type="checkbox"/> Affidavits/declaration(s)  <input type="checkbox"/> Extension of Time Request  <input type="checkbox"/> Express Abandonment Request  <input checked="" type="checkbox"/> Information Disclosure Statement  <input type="checkbox"/> Certified Copy of Priority Document(s)  <input type="checkbox"/> Response to Missing Parts/ Incomplete Application  <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application)  <input type="checkbox"/> Drawing(s)  <input type="checkbox"/> Licensing-related Papers  <input type="checkbox"/> Petition  <input type="checkbox"/> Petition to Convert to a Provisional Application  <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address  <input type="checkbox"/> Terminal Disclaimer  <input type="checkbox"/> Request for Refund  <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group  <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences  <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)  <input type="checkbox"/> Proprietary Information  <input type="checkbox"/> Status Letter  <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):  <b>Form HDP-1449 with references cited (21 Foreign Patent Documents; 13 Other Documents; 1 Intl Search Rep.); and Acknowledgment Postcard</b>
<b>Remarks</b>		<b>The Commissioner is hereby authorized to charge any additional fees that may be required under 37 CFR 1.16 or 1.17 to Deposit Account No. 08-0750. A duplicate copy of this sheet is enclosed.</b>
<b>EV 406 076 697 US</b>		

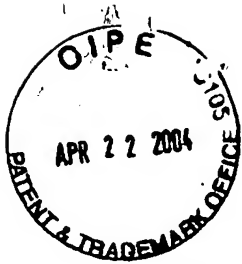
### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

<b>Firm or Individual name</b>	Harness, Dickey & Pierce, P.L.C.	<b>Attorney Name</b>	Michael Malinzak	<b>Reg. No.</b>	43,770
<b>Signature</b>					
<b>Date</b>	April 22, 2004				

### CERTIFICATE OF MAILING/TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service as express mail in an envelope addressed to: Director of the U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, or facsimile transmitted to the U.S. Patent and Trademark Office on the date indicated below.

<b>Typed or printed name</b>	Michael Malinzak	<b>Express Mail Label No.</b>	EV 406 076 697 US (4/22/2004)
<b>Signature</b>		<b>Date</b>	April 22, 2004



**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No.: 10/735,449  
Filing Date: 12-12-03  
Applicant: Shawn D. Roman et al.  
Group Art Unit: 3731  
Examiner: Unknown  
Title: CRANIAL CLAMP WITH TORQUE-LIMITING FEATURE  
Attorney Docket: 5490-000259/COB

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Director of the United States Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant hereby submits an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS, AND OTHER INFORMATION

The patents, publications and other information requested to be considered by the Office (except unpublished U.S. patent applications) are listed on Form 1449 attached hereto.

II. COPIES

A. \_\_\_\_\_ Submitted herewith is a legible copy of (i) each U.S. patent application publication and U.S. and foreign patent; (ii) each publication or that portion which caused it to be listed; (iii) for each cross-referenced pending U.S. application listed below in Section IV, the application specification including the claims, and any drawing of the application which caused it to be listed including the claims directed to that portion; and (iv) all other information or that portion which caused it to be listed.

B. \_\_\_\_\_ Any patents, publications or other information which are listed on Form 1449 or on the copies of PTO-892, but which are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Serial Number

U.S. Filing Date

C. X Because the present application was/is being filed after June 30, 2003, no copies of the U.S. patents or U.S. patent application publications which are listed on the attached Form 1449 are enclosed pursuant to the waiver of 37 C.F.R. § 1.98(a)(2)(i). Any foreign patent documents or non-patent literature listed on the attached Form 1449 are enclosed herewith.

D. \_\_\_\_ This is a PCT application in the entry of the National Phase in the United States. A copy of the International Search Report is attached for the Examiner's information. The documents listed on the International Search Report are listed on the attached Form-1449 for consideration by the Examiner and for listing on any patent resulting from this application. If the International Search Report was from the US, EPO, or JPO search authorities, copies of these references should have been supplied to the USPTO under the trilateral agreement and are believed to be in the file of the above-identified application. (MPEP 1893.03(g))

III. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

A. \_\_\_\_ Except as may be indicated below in (B), all of the patents, publications or other information are in the English language (concise explanation not required).

B. X A concise explanation of the relevance of each patent, publication or other information listed that is not in the English language is as follows (see 37 C.F.R. § 1.98(a)(3)):

1. \_\_\_\_ See the attached foreign patent office communication from a counterpart foreign application.
2. \_\_\_\_ English translations are provided.
3. X Other: **English language Abstracts are provided, except as noted in "C" below.**

C. X The following additional information is provided for the Examiner's consideration. **An International Search Report for PCT/US03/18624 is provided for the Examiner's information.**

While Applicants do not possess a translation of DE 1 089 116, it appears to disclose a bone attachment mechanism having bone engaging members 4 and 5.

While Applicants do not possess a translation of DE 2 125 556, it appears to disclose a form of a spiked staple.

IV. CROSS REFERENCE TO RELATED APPLICATION(S)

A. X The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this(these) application(s) to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. § 122.

Serial No.  
PCT/US03/18624

Filing Date  
6-12-03

Art Unit

V. THIS IDS IS BEING FILED UNDER

A. X **37 C.F.R. § 1.97(b):** (check only one box)

1. \_\_\_\_ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. § 1.97(b)(1)). No fee or certification is required.

2. \_\_\_\_ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or certification is required.

3. X before the mailing of a first Office Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below; or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

4. \_\_\_\_ before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No fee or certification is required.

B. \_\_\_\_ **37 C.F.R. § 1.97(c):** (check only one box)

before the mailing date of either any Final Office Action under 37 C.F.R. § 1.113, a Notice of Allowance under 37 C.F.R. § 1.311, or an action that otherwise closes prosecution.

1. \_\_\_\_ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

2. \_\_\_\_ See the certification below. No fee is required.

C. 37 C.F.R. § 1.97(d):

after the mailing date of either a Final Office Action under 37 C.F.R. § 1.113 or a Notice of Allowance under 37 C.F.R. § 1.311, yet on or before payment of the issue fee.

1. See the certification below. A fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).

VI. CERTIFICATION UNDER 37 C.F.R. § 1.97(e): (check only one box)

The undersigned hereby certifies that:

A. each item of information contained in this IDS was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(1)). See further statement under 37 C.F. R. 1.704(d) below in section VII, if applicable; or

B. no item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS (See 37 C.F.R. § 1.97(e)(2)).

C. Some of the items of information were first cited in a communication from a foreign patent office. As to this information, the undersigned hereby certifies that each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in this IDS was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this IDS.

VII. STATEMENT UNDER 37 CFR 1.704(d)

The undersigned hereby states that:

each item of information contained in this IDS was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this IDS.

VIII. PAYMENT OF FEES (check only one box)

A. \_\_\_\_ A check in the amount of \$180.00 is enclosed for the above-identified fee.

B. \_\_\_\_ Please charge Deposit Account No. 08-0750 in the amount of \$180.00 for the above-indicated fee. A duplicate copy of this paper is attached.

The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art, contain matter which anticipates the invention, or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art. Furthermore, this Information Disclosure Statement shall not be construed as a representation that a search has been made.

If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 08-0750.

Please charge any additional fees or credit any overpayment pursuant to 37 C.F.R. § 1.16 or § 1.17 to Deposit Account No. 08-0750.

Respectfully submitted,

Dated:

April 22, 2002

By:

Michael Malinzak  
Michael Malinzak, Reg. No. 43,770

HARNESS, DICKEY & PIERCE, P.L.C.  
P.O. Box 828  
Bloomfield Hills, Michigan 48303  
(248) 641-1600

MM/ca

FORM HDP-1449 (Based on Form PTO-1449)

PATENT AND TRADEMARK OFFICE

**INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)

Sheet 1 of 6

ATTORNEY DOCKET No.

SERIAL No.

5490-000259/COB

10/735,449

APPLICANT

Shawn D. Roman et al.

FILING DATE

GROUP

12-12-03

3731

**U.S. PATENT DOCUMENTS**

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
1.		276,135	04/1883	Cooley		
2.		741,747	10/1903	Walz		
3.		1,105,105	07/1914	Sherman		
4.		1,390,485	09/1921	Bell		
5.		1,510,416	09/1924	Pietz, et al.		
6.		1,616,232	02/1927	Roberts, et al.		
7.		2,077,804	04/1937	Morrison		
8.		2,238,238	04/1941	Westrope		
9.		2,329,471	09/1943	King		
10.		2,489,870	11/1949	Dzus		
11.		2,494,229	01/1950	Collison		
12.		2,511,051	06/1950	Dzus		
13.		2,576,649	11/1951	Slind		
14.		2,791,868	05/1957	Viken		
15.		2,846,744	08/1958	Becker		
16.		3,019,887	02/1962	Lowden		
17.		3,281,171	10/1966	Hughes		
18.		3,547,114	12/1970	Haboush		
19.		3,712,357	01/1973	Corbett, et al.		
20.		3,741,205	06/1973	Markolf, et al.		
21.		3,779,240	12/1973	Kondon		

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM HDP-1449 (Based on Form PTO-1449)

PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Sheet 2 of 6

ATTORNEY DOCKET NO.

SERIAL NO.

5490-000259/COB

10/735,449

APPLICANT

Shawn D. Roman et al.

FILING DATE

GROUP

12-12-03

3731

U.S. PATENT DOCUMENTS

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
22.		3,790,507	02/1974	Hodosh		
23.		3,875,936	04/1975	Volz		
24.		4,033,243	07/1977	Kirrish, et al.		
25.		4,116,200	09/1978	Braun, et al.		
26.		4,219,015	08/1980	Steinemann		
27.		4,245,545	01/1981	Freeman		
28.		4,275,490	06/1981	Bivins		
29.		4,360,025	11/1982	Edwards		
30.		4,503,848	03/1985	Caspar, et al.		
31.		4,643,610	02/1987	Bien		
32.		4,651,724	03/1987	Berentey, et al.		
33.		4,669,473	06/1987	Richards, et al.		
34.		4,683,878	08/1987	Carter		
35.		4,688,561	08/1987	Reese		
36.		4,793,335	12/1988	Frey, et al.		
37.		4,802,477	02/1989	Gabbay		
38.		4,875,815	10/1989	Phillips, II		
39.		4,903,691	02/1990	Heinl		
40.		4,905,679	03/1990	Morgan		
41.		4,905,680	03/1990	Tunc		

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.





FORM HDP-1449 (Based on Form PTO-1449)

**PATENT AND TRADEMARK OFFICE  
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(Use several sheets if necessary)

Sheet 3 of 6

ATTORNEY DOCKET No.

SERIAL No.

5490-000259/COB

10/735,449

APPLICANT

Shawn D. Roman et al.

FILING DATE

GROUP

12-12-03

3731

**U.S. PATENT DOCUMENTS**

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
42.		4,923,471	05/1990	Morgan		
43.		4,988,351	01/1991	Paulos, et al.		
44.		5,013,316	05/1991	Goble, et al.		
45.		5,087,202	02/1992	Krenkel		
46.		5,098,433	03/1992	Freedland		
47.		5,139,497	08/1992	Tilghman, et al.		
48.		5,167,665	12/1992	McKinney		
49.		5,196,016	03/1993	Buser, et al.		
50.		5,201,737	04/1993	Leibinger, et al.		
51.		5,250,049	10/1993	Michael		
52.		5,268,001	12/1993	Nicholson, et al.		
53.		5,269,784	12/1993	Mast		
54.		5,342,393	08/1994	Stack		
55.		5,346,492	09/1994	Morgan		
56.		5,350,399	09/1994	Erlebacher, et al.		
57.		5,352,229	10/1994	Goble, et al.		
58.		5,372,598	12/1994	Luhr, et al.		
59.		5,433,053	07/1995	Tulloch		
60.		5,433,719	07/1995	Pennig		
61.		5,468,242	11/1995	Reisberg		

Examiner:

Date Considered:

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FORM HDP-1449 (Based on Form PTO-1449)

**PATENT AND TRADEMARK OFFICE  
INFORMATION DISCLOSURE CITATION**

(Use several sheets if necessary)

Sheet 4 of 6

ATTORNEY DOCKET NO.

5490-000259/COB

SERIAL NO.

10/735,449

APPLICANT

Shawn D. Roman et al.

FILING DATE

12-12-03

GROUP

3731

**U.S. PATENT DOCUMENTS**

Ref. Desig.	Examiner's Initials	Document Number	Date	Name	Class/ Subclass	(If appropriate) Filing Date
62.		5,501,685	03/1996	Spetzler		
63.		5,549,620	08/1996	Bremer		
64.		5,578,036	11/1996	Stone, et al.		
65.		5,601,558	02/1997	Torrie, et al.		
66.		5,669,912	09/1997	Spetzler		
67.		5,707,373	01/1998	Sevrain, et al.		
68.		5,722,976	03/1998	Brown		
69.		5,741,282	04/1998	Anspach, III et al.		
70.		5,800,436	09/1998	Lerch		
71.		5,916,200	01/1999	Eppley, et al.		
72.		5,928,244	07/1999	Tovey, et al.		
73.		6,068,631	05/2000	Lerch		
74.		6,270,500	08/2001	Lerch		
75.		6,379,363	04/2002	Herrington et al.		

**FOREIGN PATENT DOCUMENTS**

Ref. Desig.	Examiner's Initials	Document Number	Date	Country	Class/ Subclass	Translation Yes	No
1.		DE 1 089 116	09/1960	Germany			X
2.		DE 2 125 556	06/1972	Germany			X
3.		DE 296 14 920 U1	10/1996	Germany		Abstract	

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM HDP-1449 (Based on Form PTO-1449)

**PATENT AND TRADEMARK OFFICE  
INFORMATION DISCLOSURE CITATION**

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Sheet 5 of 6

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12-12-03

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3731

**FOREIGN PATENT DOCUMENTS**

Ref. Desig.	Examiner's Initials	Document Number	Date	Country	Class/ Subclass	Translation	
						Yes	No
4.		DE 296 14 921 U1	10/1996	Germany		Abstract	
5.		DE 296 14 922 U1	10/1996	Germany		Abstract	
6.		DE 296 14 923 U1	10/1996	Germany		Abstract	
7.		DE 196 03 887 A1	08/1997	Germany		Abstract	
8.		DE 28 06 609 B1	07/1979	Germany		Abstract	
9.		H05-21954	03/1993	Japan		Abstract	
10.		H05-220714	08/1993	Japan		Abstract	
11.		0 510 390 A1	10/1992	EPO		Abstract	
12.		0 290 138	04/1987	EPO		Abstract	
13.		0 291 632	05/1987	EPO		Abstract	
14.		0 433 852	06/1991	EPO		Abstract	
15.		2 386 301	11/1978	France		Abstract	
16.		2 631 539 A1	05/1988	France		Abstract	
17.		1512584 A1	10/1989	Soviet Union		Abstract	
18.		1600713	10/1990	Soviet Union		Abstract	
19.		1655477 A1	06/1991	Soviet Union		Abstract	
20.		WO/97/01398	01/1997	PCT			X
21.		WO/97/29708	08/1997	PCT			X

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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Sheet 6 of 6

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5490-000259/COB

10/735,449

APPLICANT

Shawn D. Roman et al.

FILING DATE

GROUP

12-12-03

3731

**OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)**

Ref. Desig.	Examiner's Initials	
1.		Codman & Shurtleff, Inc., Neurosurgical Quality Instruments, Copyright, 1965, pgs. 10-13
2.		For The Few Who Know The Difference, TiMesh, Inc. (1 sheet).
3.		"Internal Fixation of Small Fractures," Technique Recommended by the AAO-ASIF Group, U. Heim & K.M. Pfeiffer, copyright Springer - Verlag, Berlin-Heidelberg, 1974, 1982 & 1988
4.		"Manual of Internal Fixation Technique," Recommended by the AO-Group, M.E. Mueller, M. Allgower & H. Willenegger, copyright Springer-Verlag, Berlin-Heidelberg, 1970.
5.		Four pages from catalog of products offered by Codman & Shurtleff, undated, disclosing Burr Hole Buttons.
6.		Translation of G 85 23 003.8 (Germany), Bone Plate, Feb. 1986, Oswald Leibinger GmbH (Owner).
7.		Hans G. Luhr, M.D., D.M.D., "Indications of Use of a Microsystem for Internal Fixation in Craniofacial Surgery," J. of Craniofacial Surgery, vol. 1, No. 1, Jan., 1990, pp. 35-52.
8.		Howmedica International, Inc., "Vitalium-Verschiedene Implantate," p. 54.
9.		Leibinger LP, "Leibinger," copyright 1995 (1 sheet).
10.		Walter Lorenz Surgical, Inc., "Surgical Instrument Catalog 5th Edition," copyright 1993, pp. 10-11.
11.		Walter Lorenz Surgical, Inc., 1.5/2.0mm Combination Titanium Osteosynthesis System, copyright 1994.
12.		Aesculap CranioFIX brochure, dated Mar. 1998, (9 sheets), along with sixteen (16) sheets of color photographs of the corresponding instruments, set forth in the brochure.
13.		Aesculap CranioFIX Titanium Clamp Instruction Manual (28 sheets) in various languages, dated Jan. 1999, along with one (1) color photograph of an Aesculap CranioFIX Titanium Clamp.

Examiner:

Date Considered:

EXAMINER: Please initial if citation considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.